RESPONSE

A. Status of the Claims

Claims 38, 40-43, and 46-60 were pending at the time of the Action, with claims 51-52 and 55-60 being withdrawn. New claims 61 and 62 have been added. Claims 38 and 40-43 have been amended. No new matter was added by these amendments. Claims 38, 40-43, and 46-62 will be pending after entry of the amendment, with claim s 51-52 and 55-60 being withdrawn.

B. The Claims Are Enabled

Claims 38, 40-43, 46-50, 53, and 54 are rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. Applicant traverses this rejection.

The Examiner noted that claim 40 recited "an amino acid sequence of," which the Examiner interpreted as embracing fragments of the antigenic fragments recited in the claim. Applicant has amended claim 40 for clarity by replacing "an amino acid sequence" with "the amino acid sequence." Thus, current claim 40 recites, in part: "the amino acid sequence of: amino acids 6-28, 54-59, 135-147..."

The present specification satisfies the enablement requirement because it teaches one of skill in the art how to make and use the claimed invention without undue experimentation. The specification provides the structure of SEQ ID NO: 32, which was identified using sera from individuals with antibodies against *S. epidermidis* (*see e.g.,* Specification, para. bridging p. 56-57; Example 3, and Table 1). In other words, this sequence was identified because of a demonstrated ability to stimulate an immune response in a subject. The specification teaches that hyperimmune serum reactive antigens or antigenic fragments thereof can be made by recombinant protein expression, in vitro translation, or peptide synthesis (Specification, paragraph bridging pages 13-14; first paragraph on page 32). The antigenicity of a particular sequence can be confirmed by seeing if it is bound by antibodies in sera from individuals with

antibodies against *S. epidermidis* as described in Example 3 of the specification. Accordingly, the specification teaches a person of ordinary skill in the art how to make and use a pharmaceutical composition comprising a pharmaceutical composition comprising an isolated hyperimmune serum-reactive antigen comprising the amino acid sequence of SEQ ID NO: 32.

With respect to making and using antigenic fragments of SEQ ID NO: 32, the specification discloses numerous confirmed and predicted antigenic fragments of this sequence. In particular, the specification discloses the following fragments: amino acids 6-28, 54-59, 135-147, 193-205, 274-279, 284-291, 298-308, 342-347, 360-366, 380-386, 408-425, 437-446, 457-464, 467-477, 504-510, 517-530, 535-543, 547-553, 562-569, 573-579, 592-600, 602-613, 626-631, 638-668 and 396-449 of SEQ ID NO: 32 (*see* Table 1). The specification further discloses that antigenic fragments would be expected to have structural attributes such as alpha-helix and alpha-helix forming regions, beta-sheet and beta-sheet forming regions, turn and turn-forming regions, coil and coil-forming regions, hydrophilic regions, hydrophobic regions, alpha amphipathic regions, beta-amphipathic regions, flexible regions, surface-forming regions, substrate binding regions, and high antigenic index regions of SEQ ID NO: 32 (*see* Specification, paragraph bridging pages 27-28). Based on this disclosure, one skilled in the art could make and use numerous antigenic fragments of SEQ ID NO: 32 without undue experimentation.

Enablement does not require that every species of a generic class has to be shown in the working examples of the specification. Rather, representative examples in the specification are sufficient. MPEP § 2164.02; *see also In re Fisher*, 427 F.2d 833, 839 (CCPA 1970) (explaining that as long as the specification discloses at least one method of making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement is satisfied). In addition, enablement is not precluded by the necessity for some experimentation such as routine screening. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

The specification identifies 25 confirmed or predicted antigenic fragments of SEQ ID NO: 32. The Action provides no evidence or reasoning as to why this disclosure is not enabling. Moreover, the Action's reliance on *Rochester v. Searle* is misplaced. The patent at issue in *Rochester v. Searle* did not disclose any compounds that could be used in the claimed methods nor was there any evidence that such compounds were known. The court also found that the patent at issue did not provide any guidance that would steer the skilled practitioner toward compounds that could be used to carry out the claimed methods. This is clearly not the case with the present application, which discloses SEQ ID NO: 32 and 25 antigenic fragments thereof that can be used in the claimed pharmaceutical composition.

Applicant further notes that new claims 61 recites: "A pharmaceutical composition comprising an isolated hyperimmune serum-reactive antigen consisting of the amino acid sequence of: amino acids 6-28, 54-59, 135-147, 193-205, 274-279, 284-291, 298-308, 342-347, 360-366, 380-386, 408-425, 437-446, 457-464, 467-477, 504-510, 517-530, 535-543, 547-553, 562-569, 573-579, 592-600, 602-613, 626-631, 638-668 or 396-449 of SEQ ID NO: 32." And new claim 62 recites: "The pharmaceutical composition of claim 61, comprising the isolated hyperimmune serum-reactive antigen consisting of the amino acid sequence of amino acids 396-449 of SEQ ID NO: 32." The present Action's arguments concerning enablement do not appear applicable to these new claims.

In view of the above, the present specification contains a description sufficient to enable one skilled in the art to make and use the claimed invention without unduly extensive experimentation. Applicant, therefore, requests the withdrawal of this rejection.

C. The Claims Are Novel Over Kimmerly

Claims 38, 40-43, 46-49, and 53-54 are rejected under 35 U.S.C. § 102(b) as being anticipated by Kimmerly (AAG81977; WO200134809). The Action asserts that Kimmerly

teaches a hyperimmune serum-reactive antigen comprising a fragment of SEQ ID NO: 32 as evidenced by the alignment of AAG81977 with SEQ ID NO: 32 from position 321 to 676. Applicant traverses.

A claim cannot be anticipated by a reference if the allegedly anticipatory disclosure is not enabled. Mere naming or description of the subject matter is insufficient if it cannot be produced without undue experimentation. MPEP § 2121.01; *see also Elan Pharms, Inc. v. Mayo Found. for Med. Educ. & Research*, 304 F.3d 1221, 1228 (Fed. Cir. 2002) (stating "The anticipating reference 'must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter.'"). Kimmerly does not anticipate the current claims because Kimmerly does not provide an enabling disclosure of the claimed pharmaceutical composition.

It is evident that a person skilled in the art would not find Kimmerly to provide an enabling disclosure of the presently claimed pharmaceutical composition for several reasons. Kimmerly discloses 4454 sequences, almost all with unknown function, allegedly from S. epidermidis. Kimmerly postulates that these sequences may be useful for eliciting an immunological response, but there does not appear to be any data demonstrating such an effect. The AAG81977 sequence appears to correspond to sequence 1047 in the Kimmerly reference. Kimmerly describes sequence 1047 as a "putative peptide of unknown function." Furthermore, it appears that since sequence 1048 starts with a methionine encoded by a start codon, that Kimmerly only provided an EST analysis of the S. epidermidis genome but did not confirm that the sequence is actually translated into a protein. Kimmerly's description of vaccines on pages 33 to 35 is very general and does not identify specific sequences for such purposes.

Furthermore, Kimmerly also does not teach the particular fragments of SEQ ID NO: 32 recited in claims 61 and 62. Kimmerly, therefore, cannot anticipate these claims.

Kimmerly's guess that one or more of the over 4,000 sequences listed in the Kimmerly specification may be useful in a pharmaceutical composition is not enabling as it would require undue experimentation to test all of these sequences in the absence of any guidance in the Kimmerly specification as to which sequences would likely be immunogenic and thus useful in a pharmaceutical composition. Accordingly, the current claims are not anticipated by Kimmerly. Applicants, therefore, request the withdrawal of this rejection.

D. The Claims Are Novel Over Doucette-Stamm

Claims 38, 40-43, 46-49, and 53-54 are rejected under 35 U.S.C. § 102(e) as being anticipated by Doucette-Stamm *et al.* (U.S. 6,380,370). Applicant traverses this rejection.

As noted above, a claim cannot be anticipated by a reference if the allegedly anticipatory disclosure is not enabled. Mere naming or description of the subject matter is insufficient if it cannot be produced without undue experimentation. MPEP § 2121.01; *see also Elan Pharms, Inc. v. Mayo Found. for Med. Educ. & Research*, 304 F.3d 1221, 1228 (Fed. Cir. 2002) (stating "The anticipating reference 'must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter.'"). Doucette-Stamm does not anticipate the current claims because Doucette-Stamm does not provide an enabling disclosure of the claimed pharmaceutical composition.

Like the Kimmerly reference, Doucette-Stamm discloses thousands of sequences, almost all with unknown function, allegedly from S. epidermidis. Doucette-Stamm postulates that these sequences may be useful in pharmaceutical formulations, but there does not appear to be any data demonstrating this usefulness. In particular, Doucette-Stamm does not appear to provide any evidence that SEQ ID NO: 4318 is antigenic. Doucette-Stamm also does not teach the particular fragments of SEQ ID NO: 32 recited in claims 61 and 62.

Doucette-Stamm's guess that one or more of the thousands of listed sequences may be useful in a pharmaceutical composition is not enabling as it would require undue experimentation to test all of these sequences in the absence of any guidance in the Doucette-Stamm specification as to which sequences would likely be immunogenic and thus useful in a pharmaceutical composition. Accordingly, the current claims are not anticipated by Doucette-Stamm. Applicant, therefore, requests the withdrawal of this rejection.

E. Conclusion

Applicant believes this paper to be a full and complete response to the Office Action dated May 13, 2008. Applicant respectfully requests favorable consideration of this case in view of the above comments and amendments. Should the Examiner have any questions, comments, or suggestions relating to this case, the Examiner is invited to contact the undersigned Applicant's representative at (512) 536-5654.

Respectfully submitted,

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